## REMARKS

Of the above-presented Claims 1 - 32, previously pending Claims 1 – 4, 16, 18, and 24 are hereby or were previously cancelled, remaining Claims 13, 14, 15, and 17 are subject to a restriction requirement made final in the Final Office Action dated September 29, 2005, and the remaining device claims stand allowed. A review of the application file and the claims as last amended has revealed errors in claim numbering that are corrected above. Furthermore, amendments to Claims 13, 14, 15, and 17 are offered for reconsideration inasmuch as the amendments to these method claims render them congruent with the allowed apparatus claims.

Starting with the numbering errors, it appears that the previous amendment added two dependent claims each numbered "30" and consequently mis-numbered the following claim as "31". These claims are renumbered Claims 30 - 32 above.

Upon review of the withdrawn claims by the undersigned, it appears that Claims 1 - 4 were successfully prosecuted to allowance and appear in commonly assigned and related U.S. Patent No. 6,592,610 (copy of cover and claims pages attached). The undersigned has not investigated how this occurred, but as a result, only Claims 13 - 17 remain to be prosecuted in this application.

It appears from the prior statements of the Examiner that Claims 13 - 17 were restricted due to the absence of any recitation of the "motive suture delivery system" and presumably how it would be used in the method steps. Consequently, the method steps of the above-amended Claims 13, 14, 15, and 17 are amended to recite the "motive suture delivery system" and how it would be used in a fashion that is congruent with or parallel to the allowed device claims.

In addition, amended Claim 13 recites steps leading to detection of a generic "sensory indication" that alerts the user to halt operation of the motive suture delivery system. Amended Claim 13 is more specific than Claim 1 of the '610 patent, incorporates the "motive suture delivery system", and is a fair restatement of the use of the device of Claim 5. Amended Claims 14 and 15 (dependent upon amended Claim 13) specifically recite hearing the "audible tone emitted by the motive suture delivery mechanism" upon delivery of the suture to the suture attachment site as per device Claims 7 and 8.

Similarly, Claim 17 is amended to recite detection of a "sensory indication" that alerts the user to halt operation of the motive suture delivery system. Furthermore, Claim 17 is amended to recite that the "body" is attached to the suture and is rotated into bone to affix the suture by the motive suture delivery mechanism, whereby the suture is twisted in the process. The user observes "a substantial cessation of suture twisting accompanying complete rotation of said body into bone", and halts operation of the motive suture delivery mechanism. These recitations are parallel to the recitations of device Claim 12 and claims dependent on Claim 12.

Therefore, it is respectfully submitted that above amended Claims 13, 14, 15 and 17 are allowable per se over the prior art brought to bear in examining the parallel device claims, and that the restriction requirement should be withdrawn. It is acknowledged that such reconsideration and withdrawal is not a matter of right following making the restriction final. But doing so in light of the showing made above would properly allow these method claims, along with the allowed device claims, to appear in a single patent rather than in a further patent resulting from a still further continuation application.

It is respectfully submitted that the amended claims are supported by the specification and related device claims as demonstrated above and therefore do not recite any new matter. Moreover, it is respectfully submitted that the

amended and newly presented claims do not require a further search as they incorporate the Examiner's suggestions and prior indications of allowability of the corresponding device claims in this application and are supported by the issuance of the method Claims 1 – 4 of the related '610 patent.

It is therefore respectfully submitted that all of the remaining device and method claims amended above are therefore allowable and such action is requested. The Examiner is respectfully invited to telephone the undersigned to discuss the claims and the reasons that he may have for maintaining any of the rejections or not allowing the application for any other reason.

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Respectfully Submitted,

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(12) **United States Patent**
**Beyar**

(10) **Patent No.: US 6,592,610 B2**
(45) **Date of Patent: Jul. 15, 2003**

(54) **MEDICAL SLING PROCEDURES AND ANCHOR INSERTION METHODS AND DEVICES**

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( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 57 days.

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**Related U.S. Application Data**

(63) Continuation of application No. 09/287,867, filed on Apr. 7, 1999, now Pat. No. 6,344,446, which is a continuation-in-part of application No. 08/733,798, filed on Oct. 18, 1996, now Pat. No. 5,972,000, which is a continuation-in-part of application No. 08/622,598, filed on Mar. 26, 1996, now Pat. No. 5,807,403, which is a continuation of application No. 08/150,517, filed on Nov. 10, 1993, now Pat. No. 5,520,700.

(60) Provisional application No. 60/012,205, filed on Feb. 23, 1996, and provisional application No. 60/005,348, filed on Oct. 18, 1995.

(30) **Foreign Application Priority Data**

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(51) Int. Cl.[7] ..... **A61B 17/04**

(52) U.S. Cl. ..... **606/232**; 606/139; 128/898; 227/175.4

(58) Field of Search ..... 606/139, 232, 606/72; 227/175.4, 182.1; 128/898

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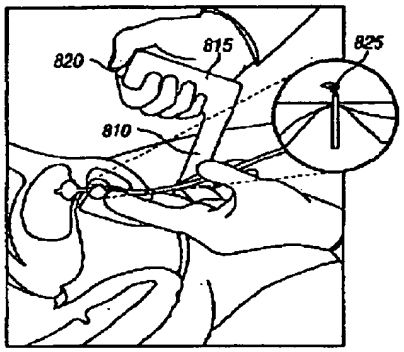
(57) **ABSTRACT**

A procedure for treating urinary stress incontinence by using bone anchors, whether screw or staple type, with or without suture, inserted pervaginally for use with a sling material for supporting the bladder neck and/or proximal urethra.

**10 Claims, 30 Drawing Sheets**



administered perioperatively for approximately 5 days after the procedure, and physical strain and lifting by the patient should be avoided for 2–3 months. In addition, it is recommended that the lot numbers of the screws used in the procedure should be recorded on the patient's chart. Upon completion of the procedure, the inserter can be discarded.

Non-Screw Bone Anchor Techniques

In alternate embodiments of the invention, the Submucosal Tunnel Technique and the Anterior Wall Dissection can be performed with a non-screw bone anchor. In the preferred embodiment, such insertions are performed using the In-Tac™ Bone Anchor System, available from Influence, Inc. of San Francisco, Calif.

In these embodiments, the procedure is also conducted using a pervaginal insertion of an anchor into the patient. After a perioperative antibiotic treatment, the patient is placed under spinal, general or local anesthesia and in the lithotomy position, and the surgical area and the vagina are cleaned and disinfected.

The anchor inserter is then loaded with an anchor. Initially, the loading key is placed into its key hole on the inserter and the key is turned clockwise approximately one half turn until the loading key will not turn further. The first anchor is then placed within the anchor inserter.

A Foley catheter is then inserted inside the bladder, and the balloon is inflated with approximately 10–20 cc of water, as previously described. The catheter is then gently pulled to locate the balloon just above the bladder neck, as shown in FIG. 27.

When the balloon 712 has been positioned, the catheter 706 is then located, within the urethra, between the physician's index and second fingers so that the finger tips are touching the balloon at the bladder neck. The physician then, by pushing his or her fingers upward and forward, presses the anterior vaginal wall against the posterior of the pubic bone 718, as shown in FIG. 28.

As shown in FIG. 44, while still feeling the catheter within the urethra, the bone anchor inserter is inserted into the vagina, below the bladder neck, lateral to the symphysis pubis, about 2 cm. to the side of the urethra, and pulled upward until the anchor housing is pressing the anterior vaginal wall against the pubic bone. The anchor shield will then retract or collapse and the tip of the bone anchor should be exposed to enable it to penetrate the vaginal wall and enter the cortex of the pubic bone, as also shown in FIG. 44.

The safety lock of the inserter is then released, and the physician pulls upwards on the handle of the inserter until an anchor is deployed. Preferably, the safety lock will not allow anchor deployment unless sufficient pressure is applied to the inserter handle. The physician can then continue with either the Submucosal Tunnel Technique or the Anterior Wall Dissection technique, as described above.

A further embodiment of the invention in which the sling material is pervaginally suspended from the pubic bone is shown in FIGS. 45(*a*) and (*b*). FIG. 45(*a*) shows a sling material wherein the sling is attached upward and forward to the mid-pubic bone, just below the Cooper's ligament. A triangle is formed by the sling material and the natural "V" of the pubic bone, providing a "free space" for the urethra which may reduce the tendency for overcorrection. FIG. 45(*b*) illustrates the sling of FIG. 45(*a*), taken as a view of the posterior pubic bone. In these embodiments, the sling material is positioned as a hammock below a portion of the female anatomy (i.e. the bladder neck and/or the urethra), the sling being suspended to the posterior surface of the pubic bone by a pervaginal technique, and with the bone anchors likewise being inserted pervaginally. In the preferred embodiment of the invention of FIG. 45, the sling is directly attached to the pubic bone without the use of intervening sutures, preferably by inserting a bone anchor through the sling material to directly attach the sling to the pubic bone.

In accordance with the inventions of the present application, one preferred sling design is shown in FIG. 46. This sling is preferably a biocompatible texturized fabric impregnated with an absorbable gelatin. It is preferred that a soft pliable material with a matrix that facilitates tissue ingrowth be used. The material can be formed with a warp knitting process. Gelatin impregnation is preferably crosslinked to a set level to control the resorption rate and reduce the potential for inflammation. The sling is also preferably prepunctured to facilitate the threading of suture or insertion of a bone anchor therethrough. In one preferred embodiment, the sling is approximately 5.5 cm in length and approximately 2 cm in width at its widest portion.

Having described this invention with regard to specific embodiments, it is to be understood that the description is not meant as a limitation since further variations or modifications may be apparent or may suggest themselves to those skilled in the art. It is intended that the present application cover such variations and modifications as fall within the scope of the appended claims.

I claim:

1. A method of treating a female patient for urinary stress incontinence, comprising:

per vaginally inserting a bone anchor to enter the posterior wall of the pubic bone, said bone anchor comprising suture thread secured thereto; and,

using said suture thread and a sling to treat the incontinence.

2. A method as claimed in claim 1, wherein said suture thread and said sling are used to position the bladder neck of the patient.

3. A method as claimed in claim 1, wherein said suture thread and said sling are used to position the urethra of the patient.

4. A method as claimed in claim 1, wherein said suture thread and said sling are used to position the bladder neck and the urethra of the patient.

5. A device for placing a bone anchor into a patient comprising:

a grasping section;

an anchor deployment section sized and shaped for placement transvaginally in said patient;

an intermediate section connecting said grasping section and said deployment section, the intermediate section having opposite sides;

said grasping section and said anchor deployment section extending from the same side of said intermediate section and wherein said grasping section and said intermediate section are free from axial alignment; and,

wherein a straight line drawn substantially orthogonal from said deployment section intersects an axis of said grasping section.

6. A device according to claim 5, wherein said grasping section extends substantially perpendicularly from said intermediate section.

7. A method of placing a bone anchor in a patient comprising:

providing a surgical instrument for delivering a bone anchor in a delivery direction;

urging said bone anchor into said patient by pulling said surgical instrument in a direction substantially parallel to said delivery direction; and,

a user's operating grasp being substantially perpendicular to said delivery direction during said pulling.

8. A device for placing a bone anchor in a patient comprising:

a grasping section;

an anchor deployment section sized and shaped for placement transvaginally in said patient;

an intermediate section connecting said grasping section and said deployment section;



said grasping section extending from said intermediate section; and,

said deployment section and said intermediate section being substantially perpendicular.

9. A device according to claim 8, wherein said deployment section includes a mount for a bone anchor.

10. A device according to claim 9, wherein said mount includes a retractable shield.

* * * * *